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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. APOTEX CORP., APOTEX INC. and APOTEX PHARMACHEM INC., Defendants.	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Apotex Corp., Apotex Inc. and Apotex Pharmachem Inc. (collectively, "Apotex"), alleges as follows:

THE PARTIES

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. Upon information and belief, Apotex Inc. is a corporation organized and existing under the laws of the Canada, having its principal place of business at 150 Signet Drive, North York, Ontario, Canada M9L IT9.

4. Upon information and belief, Apotex Pharmachem Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 34 Spalding Drive, Brantford, Ontario, Canada N3T 6B8.

NATURE OF THE ACTION

5. This is an action for infringement of U.S. Patent No. 8,017,615 ("the '615 patent"), U.S. Patent No. 8,580,796 ("the '796 patent"), U.S. Patent No. 8,642,760 ("the '760 patent") and U.S. Patent No. 8,759,350 (the '350 patent), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq*., including 35 U.S.C. §§ 271 and 281. This action relates to Apotex Inc.'s filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, import, offer to sell and sell generic pharmaceutical products ("Apotex Inc.'s generic products") prior to the expiration of the asserted patents.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has jurisdiction over Apotex Corp. Upon information and belief, Apotex Corp. is in the business of manufacturing, marketing, importing and selling

pharmaceutical drug products, including generic products. Upon information and belief, Apotex Corp., directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex Corp. "boast[s] over a billion dollars in sales—and a new ranking in the top 10 generic pharmaceutical companies according to recent IMS HEALTH data." Upon information and belief, Apotex Corp. is registered in the State of New Jersey (No. 5003192) as a drug Wholesaler. Apotex Corp. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

8. This Court has jurisdiction over Apotex Inc. Upon information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Apotex Inc., directly or through its subsidiaries, affiliates and/or agents, including Apotex Corp., manufactures, markets, imports, and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex Inc. purposefully has conducted and continues to conduct business, directly or through its subsidiaries, affiliates and/or agents, including Apotex Corp., in this judicial district and this judicial district is a likely destination of Apotex Inc.'s generic products. Upon information and belief, Apotex Inc. and Apotex Corp. share a common corporate director. Apotex Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

9. This Court has jurisdiction over Apotex Pharmachem Inc. Upon information and belief, Apotex Pharmachem Inc., directly or indirectly, is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products.

Upon information and belief, Apotex Pharmachem Inc., directly or indirectly, manufactures, markets and sells generic drug products throughout the United States and this judicial district. Upon information and belief, Apotex Pharmachem Inc.'s "manufacturing facilities allow Apotex Pharmachem to simultaneously manufacture up to ten different active pharmaceutical ingredients at its Brantford, Ontario facility." *See* http://www.apotexpharmachem.com/manufacturing.html. Upon information and belief, Apotex Pharmachem Inc. is the DMF holder for Apotex's aripiprazole API. *See* http://www.registrarcorp.com/drug/dmf-sample/type2/Aripiprazole?lang=en. Upon information and belief, Apotex Pharmachem Inc. is registered (No. 5004646) as a Drug Manufacturer in the State of New Jersey.

10. Upon information and belief, Apotex Corp., Apotex Inc. and Apotex Pharmachem Inc. operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States including in this judicial district. Upon information and belief, Apotex Inc. describes Apotex Inc. and its affiliates as a "vertically integrated company" with a "preference . . . to develop, manufacture and market [its] own products – from API to finished dosage form to marketing and distribution." *See* http://www.apotex.com/global/bd/namerica.asp.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § l400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

12. The U.S. Patent and Trademark Office ("PTO") issued the '615 patent on September 13, 2011, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '615 patent is attached as Exhibit A.

13. Otsuka is the owner of the '615 patent by virtue of assignment.

14. The ’615 patent expires on December 16, 2024 (including pediatric exclusivity).

15. The ’615 patent is directed to and claims, *inter alia,* pharmaceutical solid oral preparations, and processes for preparing pharmaceutical solid oral preparations.

16. Otsuka is the holder of New Drug Application (“NDA”) No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002.

17. Otsuka lists the ’615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-436.

18. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify®.

19. Upon information and belief, Apotex Inc. submitted ANDA No. 78-583 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell Apotex Inc.’s generic products in the United States.

20. Otsuka received a letter from Apotex Inc. dated November 12, 2014, purporting to include a Notice of Certification for ANDA No. 78-583 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) (“Apotex Inc.’s 78-583 letter”) as to the ’615 patent.

21. Apotex Inc.’s 78-583 letter alleges that the name of the drug product that is subject of the Apotex Inc. ANDA is “Aripiprazole Tablets, 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg.”

22. Upon information and belief, Apotex Inc.’s generic products will, if approved and marketed, infringe at least one claim of the ’615 patent.

23. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex Inc. has infringed at least one claim of the ’615 patent by submitting, or causing to be submitted to the

FDA, ANDA No. 78-583 seeking approval to manufacture, use, import, offer to sell and sell Apotex Inc.'s generic products before the expiration date of the '615 patent.

24. Upon information and belief, Apotex Inc.'s actions relating to Apotex Inc.'s ANDA No. 78-583 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Apotex Corp., Apotex Inc. and Apotex Pharmachem Inc.

SECOND COUNT FOR PATENT INFRINGEMENT

25. Otsuka realleges, and incorporates in full herein, paragraphs 16–21.

26. The PTO issued the '796 patent on November 12, 2013, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '796 patent is attached as Exhibit B.

27. Otsuka is the owner of the '796 patent by virtue of assignment.

28. The '796 patent expires on March 25, 2023 (including pediatric exclusivity).

29. The '796 patent is directed to and claims, *inter alia*, aripiprazole crystals.

30. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-436.

31. Apotex Inc.'s 78-583 letter purports to include a Notice of Certification for ANDA No. 78-583 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '796 patent.

32. Upon information and belief, Apotex Inc.'s generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

33. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex Inc. has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-583 seeking approval to manufacture, use, import, offer to sell and sell Apotex Inc.'s generic products before the expiration date of the '796 patent.

34. Upon information and belief, Apotex Inc.'s actions relating to Apotex Inc.'s ANDA No. 78-583 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Apotex Corp., Apotex Inc. and Apotex Pharmachem Inc.

THIRD COUNT FOR PATENT INFRINGEMENT

35. Otsuka realleges, and incorporates in full herein, paragraphs 16–21.

36. The PTO issued the '760 patent on February 4, 2014, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '760 patent is attached as Exhibit C.

37. Otsuka is the owner of the '760 patent by virtue of assignment.

38. The '760 patent expires on March 25, 2023 (including pediatric exclusivity).

39. The '760 patent is directed to and claims, *inter alia*, aripiprazole drug substance.

40. Otsuka lists the '760 patent in the Orange Book for NDA No. 21-436.

41. Apotex Inc.'s 78-583 letter purports to include a Notice of Certification for ANDA No. 78-583 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '760 patent.

42. Upon information and belief, Apotex Inc.'s generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

43. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex Inc. has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-583 seeking approval to manufacture, use, import, offer to sell and sell Apotex Inc.'s generic products before the expiration date of the '760 patent.

44. Upon information and belief, Apotex Inc.'s actions relating to Apotex Inc.'s ANDA No. 78-583 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Apotex Corp., Apotex Inc. and Apotex Pharmachem Inc.

FOURTH COUNT FOR PATENT INFRINGEMENT

45. Otsuka realleges, and incorporates in full herein, paragraphs 16–21.

46. The PTO issued the '350 patent on June 24, 2014, entitled "Carbostyril Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders." A copy of the '350 patent is attached as Exhibit D.

47. Otsuka is the owner of the '350 patent by virtue of assignment.

48. The '350 patent expires on March 2, 2027, subject to any supplemental patent term adjustment.

49. The '350 patent is directed to and claims, *inter alia,* pharmaceutical compositions and methods of treatment.

50. Otsuka lists the '350 patent in the Orange Book for NDA No. 21-436.

51. Apotex Inc.'s 78-583 letter purports to include a Notice of Certification for ANDA No. 78-583 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c)(1) as to the '350 patent.

52. Upon information and belief, Apotex Inc.'s generic products will, if approved and marketed, infringe at least one claim of the '350 patent.

53. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim of the '350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-583 seeking approval to manufacture, use, import, offer to sell and sell Apotex Inc.'s generic products before the expiration of the '350 patent.

54. Upon information and belief, Apotex Inc.'s actions relating to Apotex Inc.'s ANDA No. 78-583 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Apotex Corp., Apotex Inc. and Apotex Pharmachem Inc.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Apotex on the patent infringement claims set forth above and respectfully requests that this Court:

1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim of the '615 patent through Apotex Inc.'s submission of ANDA No. 78-583 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Apotex Inc.'s generic products in the United States before the expiration of the '615 patent;

2) order that the effective date of any approval by the FDA of Apotex Inc.'s generic products be a date that is not earlier than the expiration of the '615 patent, or such later date as the Court may determine;

3) enjoin Apotex from the manufacture, use, import, offer for sale and sale of Apotex Inc.'s generic products until the expiration of the '615 patent, or such later date as the Court may determine;

4) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex Inc.'s ANDA No. 78-583 until expiration of the '615 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim of the '796 patent through Apotex Inc.'s submission of ANDA No. 78-583 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell

Apotex Inc.'s generic products in the United States before the expiration of the '796 patent;

6) order that the effective date of any approval by the FDA of Apotex Inc.'s generic products be a date that is not earlier than the expiration of the '796 patent, or such later date as the Court may determine;

7) enjoin Apotex from the manufacture, use, import, offer for sale and sale of Apotex Inc.'s generic products until the expiration of the '796 patent, or such later date as the Court may determine;

8) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex Inc.'s ANDA No. 78-583 until expiration of the '796 patent;

9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim of the '760 patent through Apotex Inc.'s submission of ANDA No. 78-583 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Apotex Inc.'s generic products in the United States before the expiration of the '760 patent;

10) order that the effective date of any approval by the FDA of Apotex Inc.'s generic products be a date that is not earlier than the expiration of the '760 patent, or such later date as the Court may determine;

11) enjoin Apotex from the manufacture, use, import, offer for sale and sale of Apotex Inc.'s generic products until the expiration of the '760 patent, or such later date as the Court may determine;

12) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex Inc.'s ANDA No. 78-583 until expiration of the '760 patent;

13) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Apotex has infringed at least one claim of the '350 patent through Apotex Inc.'s submission of ANDA No. 78-583 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Apotex Inc.'s generic products in the United States before the expiration of the '350 patent;

14) order that the effective date of any approval by the FDA of Apotex Inc.'s generic products be a date that is not earlier than the expiration of the '350 patent, or such later date as the Court may determine;

15) enjoin Apotex from the manufacture, use, import, offer for sale and sale of Apotex Inc.'s generic products until the expiration of the '350 patent, or such later date as the Court may determine;

16) enjoin Apotex and all persons acting in concert with Apotex, from seeking, obtaining or maintaining approval of Apotex Inc.'s ANDA No. 78-583 until expiration of the '350 patent;

17) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and

18) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

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